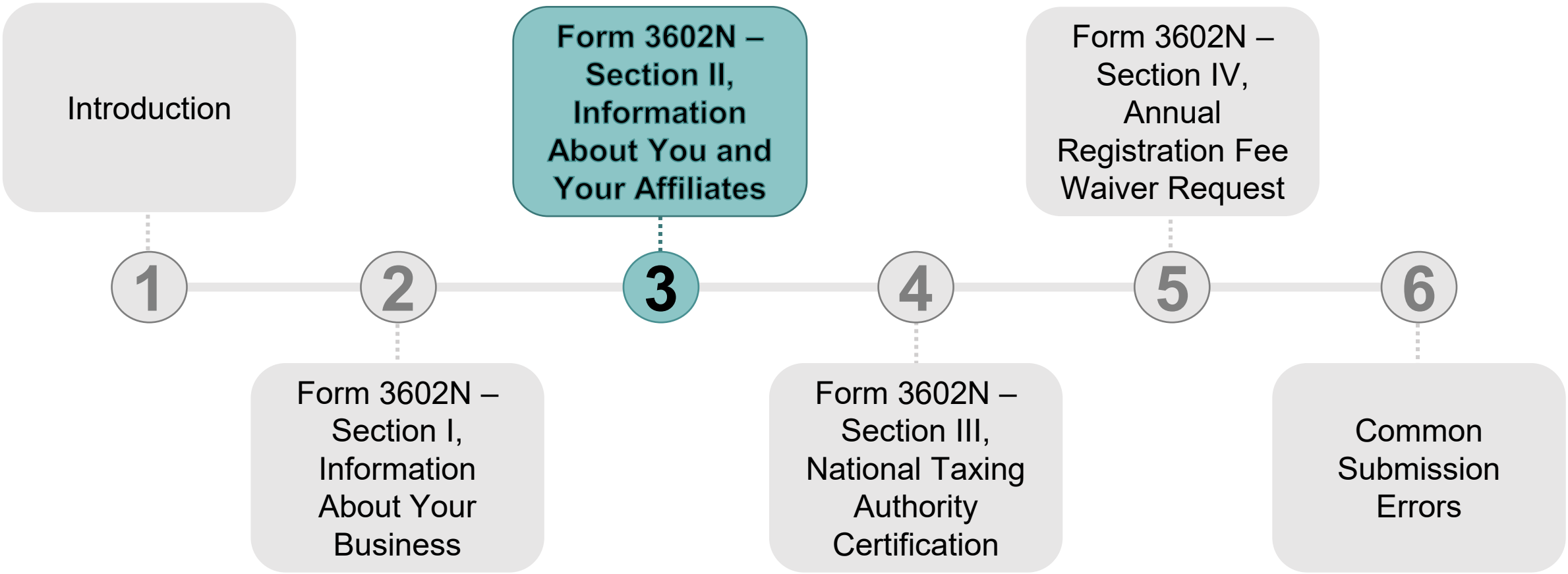
Form 3602N – Section II

Information About You and Your Affiliates

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Division of Industry and Consumer Education (DICE)

Navigating the Small Business Determination (SBD) Program Series



Navigating this Module

- Information boxes are color coded

Yellow box content applies to **both**
- U.S business applicants
- Foreign (non-U.S.) business applicants.

Blue box content applies to **U.S. business** applicants.

Green box content applies to **foreign (non-U.S.) business** applicants.

Section II

Section II provides space for information about:

- your business, and
- your affiliate businesses.

Find form “3602N” here.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14.				$
15.				$
16.				$
17.				$
18.				$
19.				$
20.				$
21.	**Total Gross Receipts or Sales Used to Determine Qualification as a Small Business** (sum of lines 1 through 20 inclusive)			$ 0.00

Federal (U.S.) income tax returns for all U.S. businesses and affiliates, and/or National Taxing Authority Certifications (Section III) for all non-U.S. businesses and affiliates identified above, must be included with this MDUFA Small Business Request.

Section II

An "affiliate" is a business entity that has a relationship with a second business entity if, directly or indirectly:

- one business entity controls, or has the power to control, the other business entity; **or**
- a third party controls, or has power to control, both of the business entities.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14.				$
15.				$
16.				$
17.				$
18.				$
19.				$
20.				$
21.	Total Gross Receipts or Sales Used to Determine Qualification as a Small Business (sum of lines 1 through 20 inclusive)			$ 0.00

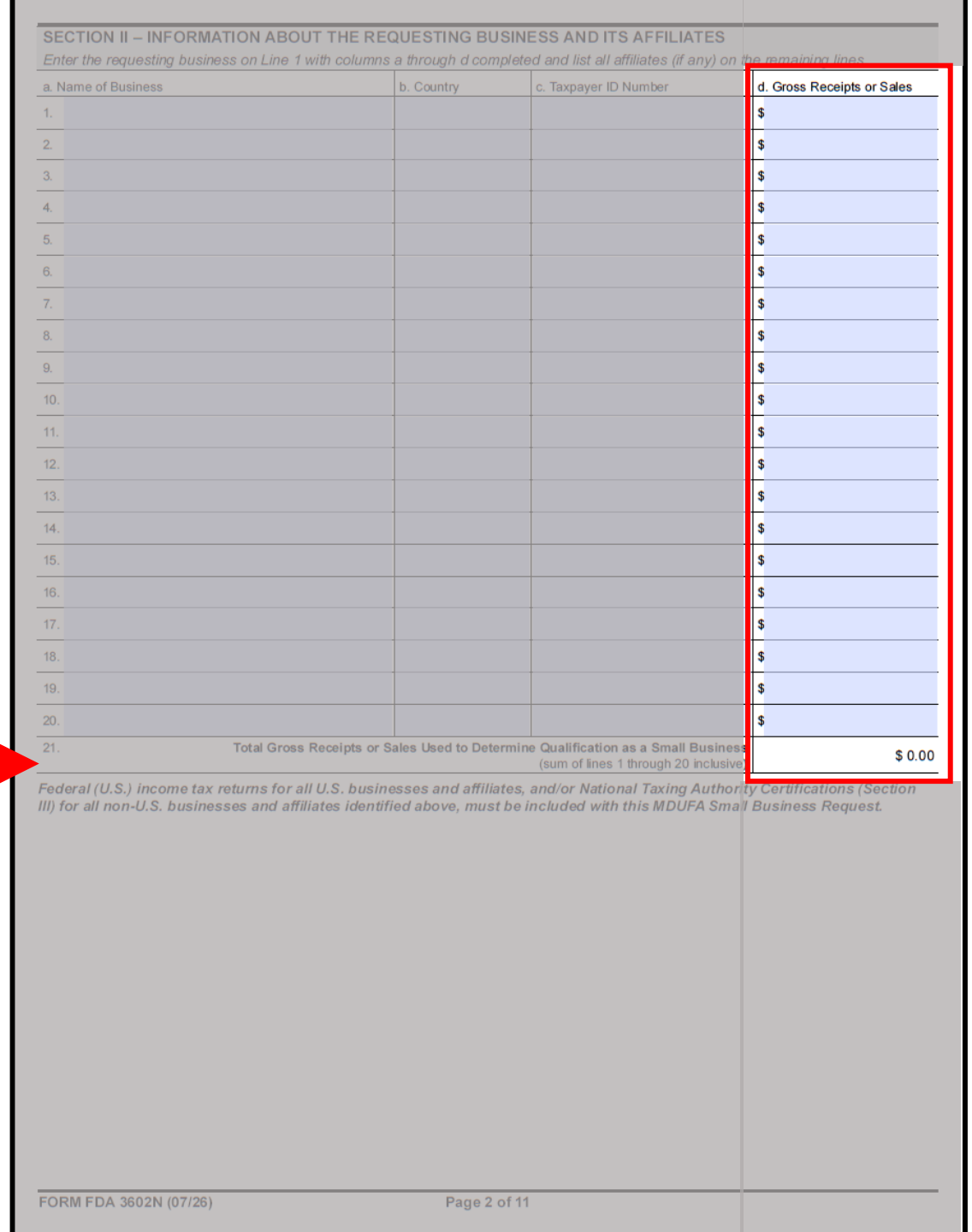
Federal (U.S.) income tax returns for all U.S. businesses and affiliates, and/or National Taxing Authority Certifications (Section III) for all non-U.S. businesses and affiliates identified above, must be included with this MDUFA Small Business Request.

Section II

Column “d”, Line 21 of Section II is designed to auto-calculate the total sum of gross receipts or sales for your business and its affiliates.

If you have more than 19 affiliates: Print enough copies of Section II and manually write in the gross receipts or sales.

Add the total amount in Line 21.



SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14.				$
15.				$
16.				$
17.				$
18.				$
19.				$
20.				$
21.	Total Gross Receipts or Sales Used to Determine Qualification as a Small Business (sum of lines 1 through 20 inclusive)			$ 0.00

Federal (U.S.) income tax returns for all U.S. businesses and affiliates, and/or National Taxing Authority Certifications (Section III) for all non-U.S. businesses and affiliates identified above, must be included with this MDUFA Small Business Request.

FORM FDA 3602N (07/26) Page 2 of 11

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business			
1.				
2.				
3.				
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14.				$

Input the **full legal name of your business**.

This name must match the name of the business you listed in your User Fee System account.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c.	es
1.				
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input the **country** where the business is physically located.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.			$
2.			$
3.			$
4.			$
5.			$
6.			$
7.			$
8.			$
9.			$
10.			$
11.			$
12.			$
13.			$
14.			$

Input **your business's** Taxpayer ID Number.

U.S. businesses:

Input the Employer Identification Number (EIN) from your business's Federal (U.S.) income tax return.

Foreign businesses:

Input the number assigned to your business by your country's National Taxing Authority.

If your country does not have a National Taxing Authority, input "No NTA".

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Busi	d. Gross Receipts or Sales
1.		$
2.		$
3.		$
4.		$
5.		$
6.		$
7.		$
8.		$
9.		$
10.		$
11.		$
12.		$
13.		$
14		$

Input **your business's** gross receipts or sales in U.S. dollars.

U.S. businesses:

Find the amount in your most recent Federal (U.S.) income tax return.

IRS Form	See Line Number
Schedule C (Form 1040)	1
Form 1065	1a
Form 1065-B	1a
Form 1120	1a
Form 1120-F	Section II, 1a
Form 1120S	1a
Form 990	12

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Busi			d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input **your business's** gross receipts or sales in U.S. dollars.

Foreign businesses:

Provide the amount you reported to your National Taxing Authority for the most recent tax year and convert it to U.S. dollars.

Use the exchange rate from the end date of the period when receipts or sales were collected.

- Show the exchange rate you used in Section III of Form 3602N.
- Contact your National Taxing Authority to determine the correct rate to use.
- The FDA cannot provide exchange rate information.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b		
1.				
2.				
3.				
4.				
5.				
6.				
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

List your **business's affiliates** in lines 2 – 20.

Input the **full legal name** of each affiliate.

<u>If you have more than 19 affiliates</u>:
Continue listing them starting on Line 2 of the additional page(s).

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c	les
1.				
2.				
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input the country where the **affiliate business** is physically located.

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input your **affiliate business's** Taxpayer ID Number.

U.S. affiliates:

Input the Employer Identification Number (EIN) from the business's Federal (U.S.) income tax return.

Foreign affiliates:

Input the number assigned to the business by the affiliate's National Taxing Authority.

If the affiliate's country does not have a National Taxing Authority, input "No NTA".

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input your **affiliate business**'s gross receipts or sales in U.S. dollars.

U.S. businesses:

Find the amount from the affiliate's most recent Federal (U.S.) income tax return.

IRS Form	See Line Number
Schedule C (Form 1040)	1
Form 1065	1a
Form 1065-B	1a
Form 1120	1a
Form 1120-F	Section II, 1a
Form 1120S	1a
Form 990	12

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14				$

Input your **affiliate business**'s gross receipts or sales in U.S. dollars.

Foreign businesses:

Provide the amount your affiliate reported to their National Taxing Authority for the most recent tax year and convert it to U.S. dollars.

Use the exchange rate from the end date of the period when receipts or sales were collected.

- Show the exchange rate used in Section III of Form 3602N.
- Contact the National Taxing Authority to determine the correct rate to use.
- The FDA cannot provide exchange rate information.

Next Step: Section III of Form 3602N

- To continue filling Form 3602N with step-by-step instructions, go to the CDRH Learn module "Form 3602N – Section III".

Resources

Slide #	Cited Resource	URL
4	Download Form FDA 3602N	https://www.fda.gov/about-fda/reports-manuals-forms/forms
7	User Fee System webpage	https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=mdufa
17	CDRH Learn	https://www.fda.gov/training-and-continuing-education/cdrh-learn
N/A	SBD program guidance document	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination
N/A	SBD program webpage	https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-or-waived-medical-device-user-fees-small-business-determination-sbd-program


FDA
U.S. FOOD & DRUG
ADMINISTRATION